

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION**

COOK INCORPORATED Corporate Parent )  
COOK GROUP INCORPORATED, )  
Plaintiff, )  
vs. )  
ENDOLOGIX, INC., )  
Defendant. )  
\_\_\_\_\_  
ENDOLOGIX, INC., )  
Counter Claimant, )  
vs. )  
COOK INCORPORATED, )  
Counter Defendants. )  
No. 1:09-cv-01248-TWP-DKL

**ENTRY ON MOTION TO EXCLUDE PORTIONS OF THE EXPERT TESTIMONY  
OF DR. GORDON K. MCLEAN**

This matter is before the Court on Defendant Endologix Inc.’s (“Endologix”) Motion to Exclude Portions of the Expert Testimony of Dr. Gordon K. McLean (“Dr. McLean”). Plaintiff Cook Incorporated (“Cook”) retained Dr. McLean and Dr. McLean submitted his expert report pursuant to Federal Rule of Civil Procedure 26(2)(B) on December 16, 2011. Endologix objects to several portions of Dr. McLean’s testimony. For the reasons set forth below, Endologix’s motion (Dkt. 188) is **GRANTED in part** and **DENIED in part**.

## **I. BACKGROUND**

The facts and background of this case are set forth at length in the Court's Entry on Claim Construction (Dkt. 145) and Entry on Endologix's Motion for Summary Judgment of Noninfringement (Dkt. 300). Additional facts relevant to the current motion will be provided.

Cook retained Dr. McLean as an expert pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), and he subsequently submitted his expert report (Dkt. 191-1). The expert report addresses Dr. McLean's academic and professional qualifications as well as experience, anticipated testimony topics, a background of the technology at issue, and detailed bases for his opinions on the accused products.

In summary, Dr. McLean opined that both accused products, the Powerlink and Intuitrak, infringed upon the patents-in-suit. In stating his opinions, Dr. McLean stood in the position of a person of ordinary skill in the art, which he defined as "an interventional radiologist or cardiologist, or a physician with at least two years equivalent experience with catheter-based technologies. This person would also have a basic understanding of engineering or medical device design principles." Dkt. 191-1 at 30–31.

Endologix has moved to exclude several portions of Dr. McLean's expert testimony, specifically arguing that Dr. McLean inappropriately opines concerning the meaning of various claim terms, and that he lacks the requisite qualifications to testify regarding the mechanical properties of the '706 patent stent assemblies and Powerlink device.

## **II. LEGAL STANDARD**

Federal Rule of Evidence 702 provides that:

[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon

sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts.

Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), and Rule 702, courts are charged with ensuring that expert testimony admitted into evidence is both reliable and relevant. “Patent cases, like all other cases, are governed by Rule 702. There is, of course, no basis for carving out a special rule as to experts in patent cases.” *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008). In *Daubert*, the Supreme Court articulated four factors to be used when assessing the reliability of expert testimony: (1) whether the theory or technique employed by the expert in formulating his expert opinion can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether standards control operation of the technique; and (4) whether the theory or technique is generally accepted within the relevant community. 509 U.S. at 593–94. However, these *Daubert* factors are not a definitive or exhaustive checklist. Instead, they must be employed flexibly “to account for the various types of potentially appropriate expert testimony.” *Deputy v. Lehman Bros., Inc.*, 345 F.3d 494, 505 (7th Cir. 2003) (citation omitted). Thus, in some cases, “the relevant reliability concerns may focus upon personal knowledge or experience.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999).

As for relevance, the opinion must assist the trier of fact with any issue involved in the case. See *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). The Court may not decide if the expert’s opinion is correct; rather, it must only determine whether the expert’s testimony is pertinent to an issue in the case. *Id.* In patent cases, expert testimony about the construction of claims is irrelevant, because claim construction “is a legal determination to be made by the Court, and not an issue of fact for the jury.” *Callpod, Inc. v. GN Netcom, Inc.*, 703

F. Supp. 2d 815, 821 (N.D. Ill. 2010). See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1995) (holding that “the construction of a patent, including terms of art within its claim, is exclusively within the province of the court”). “Expert opinions that conflict with a court’s established claim construction tend only to create confusion and are thus unhelpful to the jury.” *Callpod*, 703 F. Supp. 2d at 822.

### **III. DISCUSSION**

In its motion, Endologix first argues that Dr. McLean inappropriately opines concerning the meaning of several claim terms, including three terms in the ‘706 patent—“wire formed into a closed zig-zag configuration,” “forming a [first/second] stent from a continuous [first/second] length of wire” / ”a [first/second] wire,” and “body passageway”—and three terms in the ‘777 patent—“introducer sheath,” “substantially constant” / “uniform,” and “having a fixed shape.” Second, it argues Dr. McLean lacks the requisite knowledge, skill, experience, training, or education to assist the trier of fact concerning the mechanical properties of the stent assemblies claimed in the ‘706 patent and the Powerlink.

#### **A. Opinion Testimony Regarding Claim Terms**

To begin, the Court notes that it granted Endologix’s motion for summary judgment of noninfringement of the ‘706 patent by literal infringement (Dkt. 300). Therefore, the portions of Dr. McLean’s expert report that opine on literal infringement of the ‘706 patent are necessarily excluded from trial. These paragraphs, as objected to by Endologix, include 76–79, 80–81, 84–88, and 102–04. Therefore, Endologix’s motion is granted as to Dr. McLean’s opinions relating to literal infringement of the ‘706 patent.

**1. “Wire Formed into a Closed Zig-Zag Configuration”**

Endologix seeks to exclude Dr. McLean’s doctrine of equivalents infringement opinions in paragraphs 108–13. In paragraph 108, Dr. McLean opines “the Endologix Powerlink bifurcated stent grafts literally meet each step and element, respectively of claims 6 and 12 of the ‘706 patent. To the extent there are any differences they are insubstantial.” Dkt. 191-1 at 62–63 ¶ 108. Because the issue of literal infringement has been settled, Dr. McLean may not testify at trial that in his opinion the Powerlink literally infringes the ‘706 patent. Therefore, the opinion expressed in paragraph 108 is excluded. In paragraphs 109–13, Dr. McLean opines that the Powerlink stent structure is the equivalent of stents having a closed zig-zag configuration. The Court finds these opinions are relevant to the issue of equivalence and would be helpful to the jury. However, Dr. McLean’s testimony shall not refer to his own definitions of the claim terms found in the excluded paragraphs 80–81. Therefore, Endologix’s motion regarding paragraphs 109–13 is denied.

**2. “Introducer Sheath”**

In paragraph 124 of his report, Dr. McLean discusses the term “introducer sheath,” which the Court construed as meaning “a hollow tube extending from outside the body to define a conduit into and through a vessel in the human body.” Dkt. 145 at 43. Dr. McLean opines that the Court’s construction is “incomplete” and “overbroad as it could be understood to cover a number of other structures that are not introducer sheaths.” Dkt. 191-1 at 73 ¶ 124. He explains that

A person of ordinary skill in the art would have understood that an introducer sheath is a thin, *hollow tube that is inserted into the body at the beginning of a procedure, remains in place throughout the procedure, and serves as a conduit and primary access point for the subsequent insertion of catheters and other interventional instruments. . . .* The term “introducer” distinguishes the sheath as *the primary access sheath* for introducing devices into the vasculature. Once an

introducer sheath is placed in the body, additional sheaths may be passed through the introducer sheath, but a person of ordinary skill in the art at the time of the invention of the '777 patent, who would be familiar with catheterization techniques, would not refer to such sheaths as introducer sheaths. This is because these additional sheaths would not provide the same structure, or function, of an introducer sheath.

Dkt. 191-1 at 73–74 ¶ 124 (first emphasis added).

Endologix argues Dr. McLean's opinion reconstrues the term and "deviates dramatically from the Court's claim construction, adding a number of additional limitations to the claim." Dkt. 189 at 21. Cook responds that Dr. McLean's opinions "faithfully follow the Court's construction," pointing out Dr. McLean's deposition testimony that his characterization of the Court's construction as incomplete and overbroad "was not meant to disparage the Court's construction, but rather, to warn that the construction could be misunderstood or misapplied to cover structures that are not, in fact introducer sheaths." Dkt. 210 at 33.

The Court disagrees with Cook. During claim construction, Cook argued that the construction ultimately adopted by the Court failed to explain the meaning of "introducer" whereas its construction of "an outermost sheath defining a conduit between a body lumen to be treated and the outside of the body" gave real meaning to the term. Dkt. 145 at 28. But the Court stated that the language "defines a conduit into and through a vessel in the human body . . . adequately captures the meaning of the word 'introducer.'" Dkt. 145 at 28 (internal quotation marks omitted). Dr. McLean's opinion seeks to add to the Court's construction by giving further meaning to the word "introducer" in the claim term, something the Court has considered and rejected. *See Callpod*, 703 F. Supp. 2d at 821–22 (excluding expert testimony as irrelevant when expert's opinion was "precisely the construction of activate that the Court considered, and rejected, in its claim construction"). Cook did not succeed with its argument at claim construction and cannot seek to reargue its point at trial through expert testimony.

Therefore, the Court concludes Dr. McLean’s opinion on the meaning of “introducer sheath” would be unhelpful and confusing to the jury. Endologix’s motion regarding this opinion found in paragraph 124 of Dr. McLean’s report is granted.

### **3. “Substantially Constant” / “Uniform”**

In paragraph 125 of his report, Dr. McLean discusses the terms “substantially constant” and “uniform,” which the Court declined to construe given the relatively plain meaning of the terms. Dr. McLean opines that “these phrases mean that the inner diameter of the introducer sheath does not vary substantially over its length in a manner that would prevent the retraction of the introducer sheath over the central carrier.” Dkt. 191-1 at 74 ¶ 125.

Endologix contends that Dr. McLean’s opinion goes beyond the Court’s conclusion that the terms needed no construction. Specifically, it argues “Dr. McLean’s new construction is unsupported by the intrinsic evidence and would amount to a marked deviation from the ordinary meaning of the terms. Nothing in the ‘777 patent limits the terms . . . to an ‘inner diameter’ that ‘would prevent the retraction of the introducer sheath over the central carrier.’” Dkt. 189 at 23. Cook does not truly contest Endologix’s argument, but simply asserts “Dr. McLean’s opinions stay true to the Court’s construction of this term and will be helpful to the jury.”

The Court agrees with Endologix. At claim construction, it was Cook who argued that the terms “substantially constant” and “uniform” were “entitled to their ordinary meaning.” Dkt. 121 at 21. Cook offered no argument that the plain meaning of the terms would involve more than the “application of the widely accepted meaning of commonly understood words.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). Yet Dr. McLean’s definition of “substantially constant” and “uniform” departs from the widely accepted meaning of commonly understood words by adding a functional limitation into the meaning of the terms, specifically

requiring an inner diameter that would “prevent the retraction of the introducer sheath over the central carrier.” Dkt. 191-1 at 74 ¶ 125. Although it is “entirely proper to consider the functions of an invention in seeking to determine the meaning of particular claim language,” *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005), “where the Court concludes below that a term requires no construction, it does not invite the parties to present their arguments about that term’s meaning to the jury,” *Tomita Techs. USA, LLC v. Nintendo Co.*, \_\_ F. Supp. 2d \_\_, No. 11 Civ. 4256 (JSR), 2012 WL 612487 at \* 4 (S.D.N.Y. Feb. 22, 2012). This is especially true where, as here, Cook had an opportunity at claim construction to present any special meaning of the terms. *See Phillips*, 415 F.3d at 1316 (“[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.”); *Callpod*, 703 F. Supp. 2d at 821 (holding that when “[t]he parties did not dispute the meaning of the term [ ] during claim construction,” but later sought “to raise the issue now through [an expert’s] proposed testimony as to the meaning of the term,” allowance of that testimony is improper). Therefore, the Court concludes Dr. McLean’s opinion on the meaning of “substantially constant” and “uniform” would be unhelpful and confusing to the jury. Endologix’s motion regarding this opinion found in paragraph 125 of Dr. McLean’s report is granted.

#### **4. “Having a Fixed Shape”**

In paragraph 132 of his report, Dr. McLean discusses the term “having a fixed shape,” which the Court construed to mean “a shape that cannot change.” Dkt. 145 at 43. Dr. McLean opines that “[a] person of ordinary skill in the art would have understood that the phrase ‘having a fixed shape’ or ‘having a shape that cannot change,’ does not mean that the vascular dilator

head region is rigid or inflexible. . . . Rather, the phrase ‘having a fixed shape’ was merely added to distinguish the claimed structure from a balloon catheter, a type of dilating device that expands a vessel by changing shape.” Dkt. 191-1 at 78 ¶ 132.

At claim construction, Cook argued that “having a fixed shape” referred to an “*inflating* shape change.” The Court flatly rejected Cook’s argument and stated: “The prosecution history established that the dilator head *both* (1) has ‘a fixed shape’ and (2) ‘does not employ an inflatable balloon.’ But the prosecution history did not unequivocally redefine ‘fixed shape’ to mean the lack of an inflatable balloon.” Dkt. 145 at 32. It is clear that Dr. McLean’s opinion is “precisely the construction of [‘having a fixed shape’] that the Court considered, and rejected, in its claim construction.” *See Callpod*, 703 F. Supp. 2d at 821–22. Therefore, the Court concludes Dr. McLean’s opinion on the meaning of “having a fixed shape” would be unhelpful and confusing to the jury. Endologix’s motion regarding this opinion found in paragraph 132 of Dr. McLean’s report is granted.

## **5. Opinions Based on Improper Claim Interpretations**

Endologix further seeks to exclude testimony based on paragraphs 124, 125, and 132, in which Endologix contends Dr. McLean continues to advance his interpretations of the claim terms. Specifically, Endologix seeks to exclude paragraphs 126, 127, 131, 133, and 134. In those paragraphs, Dr. McLean opines that the Intuitrak device infringes on the ‘777 patent. Specifically, in paragraph 126, Dr. McLean describes the Intuitrak’s “introducer sheath” as defining a “conduit into and through a vessel in the human body” because it is “the primary access sheath during delivery and deployment of the Powerlink stent graft and directly contacts the arteriotomy at the access vessel site.” Dkt. 191-1 at 75 ¶ 126. He also describes how the introducer sheath is “substantially constant” / “uniform” along its length, because its dimensions

are such that “a person of ordinary skill in the art would not expect such a small change to have negative effects on the retraction of the introducer sheath over the central carrier.” Dkt. 191-1 at 75–76 ¶ 126. In paragraph 127, Dr. McLean simply states his ultimate opinion of infringement.

The Court first finds that Dr. McLean’s opinion that the Intuitrak has an “introducer sheath,” as disclosed by the ‘777 patent, does not advance an interpretation of the claim term different than the Court’s construction. Dr. McLean may testify regarding that portion of his opinion in paragraph 126. Second, Dr. McLean may testify regarding the dimensions of the Intuitrak’s “introducer sheath” to support his opinion that it has a “substantially constant” / “uniform” diameter. However, Dr. McLean’s testimony shall not reference his definition of the claim term which adds the functional limitation “in a manner that would prevent the retraction of the introducer sheath over the central carrier.” Insofar as Dr. McLean’s opinion in paragraph 126 does rely on this definition, that portion of his testimony is excluded. Third, Dr. McLean’s ultimate opinion of infringement found in paragraph 127 does not advance a claim interpretation different than the Court’s construction and is therefore not excluded. Endologix’s motion regarding the portions of Dr. McLean’s opinions found in paragraphs 126 and 127 is denied consistent with the exception set forth above.

Endologix also seeks to exclude Dr. McLean’s opinions found in paragraphs 131, 133, and 134. In paragraph 131, Dr. McLean explains that he was asked to consider how a person of ordinary skill in the art would understand “having a fixed shape.” In paragraph 133, Dr. McLean describes the Intuitrak’s tip and how the tip expands the access vessel. In paragraph 134, Dr. McLean opines that the Intuitrak infringes upon the ‘777 patent. The Court finds these paragraphs do not advance a claim interpretation different than the Court’s construction.

Therefore, the opinions found in paragraphs 131, 133, and 134 are not excluded. Endologix's motion regarding these portions of Dr. McLean's opinions is denied.

## **B. Opinion Testimony Regarding Mechanical Properties of Stent Assemblies**

### **1. Expert Opinion Regarding the '706 Stent Assembly**

Endologix contends Dr. McLean lacks the requisite knowledge, skill, experience, training, or education to opine regarding the mechanical properties of the stent assemblies claimed in the '706 patent. Specifically, Endologix seeks to exclude the following opinion:

The interlocking structure provides a single cohesive stent assembly that is capable of transmitting longitudinal and radial forces between stents, without using rigid and clumsy structures, such as longitudinal bars. This provides numerous beneficial mechanical and physical properties, including flexibility, increased column strength, reduced telescoping, and improved deployment accuracy. Unlike structures with rigid longitudinal bars, the interlocking eye assembly provides a structure with a relatively flexible linkage between the stents, thereby improving deployment and reducing the perceived risk of stent separation and device fracture.

Dkt. 191-1 at 26–27 ¶ 56. Endologix also seeks to exclude portions of Dr. McLean's rebuttal report containing similar opinions. *See* Dkt. 191-3 at 23–26, 32, 35 ¶¶ 36–39, 48, 53. Endologix argues Dr. McLean cites no authority or scientific basis for his opinions in paragraph 56, "nor could Dr. McLean have determined these properties on his own because he is a doctor and lacks any specialized training relating to the mechanical properties of the stent assemblies in the '706 patent." Dkt. 189 at 26.

### **2. Expert Opinion Regarding the Powerlink Stent Device**

Similarly, Endologix contends Dr. McLean lacks the requisite knowledge, skill, experience, training, or education to testify regarding the mechanical properties of the Powerlink. It specifically seeks to exclude the following opinion:

The linking and interlocking of stent segments within the main body, and the linking and interlocking of the main body with the limbs provides the Powerlink

bifurcated stent graft with a combination of flexibility and column strength. These properties allow the Powerlink bifurcated stent graft to be placed directly on the aortic bifurcation, a technique Endologix markets as “anatomical fixation.” In my opinion, the linking structure, and anatomical fixation, is enabled by the invention described and claimed in the ’706 patent-in-suit. In particular, the interlocking design using eyes to join bends of an adjacent stent provides the Powerlink stent graft with sufficient flexibility, durability, and column strength to allow the device to sit on the aortic bifurcation.

Dkt. 191-1 at 33 ¶ 68. Endologix also seeks to exclude similar opinions found in paragraph 51 of Dr. McLean’s rebuttal report. Endologix argues Dr. McLean cites no authority or scientific basis for this opinion, and he “admits that he did not conduct any tests, or review any tests conducted by others, relating to the mechanical properties of the Powerlink, like flexibility and column strength, and he has not had any experience testing such properties in other stents.” Dkt. 189 at 25.

### **3. Dr. McLean’s Qualifications**

To begin, the Court notes that Dr. McLean’s expert report establishes he has the requisite knowledge, skill, experience, training, and education to offer expert testimony in this case. Dr. McLean is an interventional radiologist and since 1989 has been Chief of the Vascular and Interventional Radiology Section of the Western Pennsylvania Allegheny Healthcare System. In that role, Dr. McLean has taught and trained fellows in vascular and interventional radiology. He has been active in multicenter trials for intravascular stents. He followed closely the development of stent grafts and when the first devices were released in 1999, began incorporating aortic stent grafting into his clinical practice. He has personal experience placing a variety of stent grafts, including the Zenith, which is manufactured by Cook. Furthermore, Dr. McLean has designed and developed medical devices that have been produced commercially. In the late 1980s, he designed a study that investigated the biological interactions between the stainless steel used in stents, stent-covering fabric, and the aortic wall. In making his expert

report, Dr. McLean reviewed the '706 and '777 patents, the accused devices, and documents produced by Endologix concerning the accused products. He also attended an inspection of Endologix's manufacturing plant, where he observed technicians manufacturing the Powerlink stent. He inspected and deployed an Intuitrak delivery system and the included Powerlink stent.

Based on the foregoing, the Court finds Dr. McLean has the requisite qualifications to opine about the mechanical properties of the patents-in-suit and accused device. Dr. McLean has been a teacher and practitioner in vascular and interventional radiology for over twenty-three years, and has actively engaged in designing and testing stent devices. He does not need a formal engineering degree, as suggested by Endologix, to be an expert in this field. Accordingly, the Court finds Dr. McLean is qualified to testify as an expert on the topics he addresses in his report.

#### **4. Reliability of Dr. McLean's Opinions**

In order for Dr. McLean's testimony to be admissible, it must have a reliable basis in the knowledge and experience of the relevant discipline and must fit the facts of the case. *Kumho*, 526 U.S. at 149–50. “An expert’s testimony is not unreliable simply because it is founded on his experience rather than on data; indeed, Rule 702 allows a witness to be ‘qualified as an expert by knowledge, skill, experience, training, or education.’” *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010). The Court treats the reliability of an expert’s opinion separately from his or her overall qualifications. *Bourelle v. Crown Equip. Corp.*, 220 F.3d 532, 537 (7th Cir. 2000). Even shaky expert testimony may be admissible, assailable by its opponents through cross-examination. *Metavante Corp.*, 619 F.3d at 762. However, “the expert [must] explain the ‘methodologies and principles’ that support his opinion; he cannot simply assert a ‘bottom line.’” *Id.* at 761.

The Court does not find that Dr. McLean's testimony about the '706 assemblies or Powerlink assembly is unreliable. Dr. McLean based his opinions on his own experience, observations, and knowledge. His opinions do contain citation to articles or manufacturing documents, as well as his own personal observations. This is more than simply asserting a "bottom line" opinion with no support. To the extent Endologix disagrees with Dr. McLean's conclusions or that certain portions of his testimony may be less credible, the appropriate method of challenging such testimony is through cross-examination rather than exclusion.

Endologix further moves the Court to exclude portions of Cook's proposed damages expert, Julie Davis, which are based on Dr. McLean's excluded opinions. A separate motion (Dkt. 193) on this issue has been filed and a separate ruling will follow.

#### **5. Helpfulness of Dr. McLean's Testimony**

Here, the Court finds Dr. McLean's testimony will assist the trier of fact to understand the evidence or determine a fact in issue. Endologix does not raise any argument otherwise, nor could it. The intricacies, development, function and operation of stent grafts and delivery systems is complex. Dr. McLean's testimony contains information that is not obvious to a layperson, and it will help the jury better understand this case. Therefore, Endologix's motion regarding Dr. McLean's opinions about the mechanical properties of the stent assemblies at issue is denied.

#### **IV. CONCLUSION**

For the reasons stated above, Endologix's motion (Dkt. 188) is **DENIED in part** and **GRANTED in part**. Specifically, the Court will exclude the portions of Dr. McLean's testimony regarding literal infringement of the '706 patent and construction of the terms "substantially constant" / "uniform," "introducer sheath," and "having a fixed shape." The Court

will allow Dr. McLean's testimony regarding doctrine of equivalents infringement of the '706 patent, literal infringement of the '777 patent, and the mechanical properties of the stent assemblies.

SO ORDERED.

Date: 09/06/2012



Hon. Tanya Walton Pratt, Judge  
United States District Court  
Southern District of Indiana

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